UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,651	07/02/2003	Roland Chorin	P33094	5422

7590 08/09/2006

GLAXOSMITHKLINE
Corporate Intellectual Property - UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939

EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/612,651	CHORIN ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-37 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 07/11/06.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 7-9, 11, 13-15, 17, 18, 25-27, 29 and 32-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are rejected in the use of the phrases "preferably", "more preferably", "most preferably", "advantageously", "more advantageously", "for example", "for instant", and "hereinbefore exemplified". The phrases render the claims indefinite because it is unclear whether the limitations following the phrases are part of the claimed invention. See MPEP § 2173.05(d).

Claim 13 is rejected as being of improper dependent form for failing to further limit the subject matter of claim 12. Claim 12 is narrower than claim 13 in the use of the additional component, *e.g.*, sodium lauryl sulfate.

Claim 36 provides for the use of amoxicillin, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 36 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under

35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-11, 15, 17, 18 and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Autant et al. US 6,022,562, in view of Bilke et al. US 2003/0186956 A or Kurtz et al. US 2003/0138397 A.

Autant teaches microcapsules of between 50 and 1000 µm for oral administration comprising 55-95% by weight of active principles coated with a coating composition comprising mixture of 50-90% of at least one film-forming polymer (P1), 2-25% of at least one nitrogen-containing polymer (P2), 2-20% of at least one hydrophobic plasticizer, and 2-20% of at least one surface-active and/or lubricating agent (abstract;

column 6, lines 61 through column 7, lines 1-32; and column 8, lines 22-24). Prefer coating composition comprises 60-80% ethylcellulose, 5-10% polyvinylpyrrolidone, 5-10% castor oil, and 2-8% magnesium stearate (column 10, lines 9-27). Active principles include antibiotic, antifungal, and antiviral (column 10, lines 48-50). The amount of coating composition in the microcapsules is from 5-40% of the weight of the coated microcapsules (column 11, lines 59-61). Autant further teaches the process for preparing the microcapsules (column 12, lines 1-27).

Autant does not expressly teach the claimed antibiotic.

Bilke teaches an oral pharmaceutical dosage form such as tablet comprising amoxicillin and clavulanate, and at least one excipient (paragraphs 0025-0026).

Kurtz teaches an oral composition such as tablet, capsule, and powder comprising suitable antimicrobial agent includes amoxicillin (paragraphs 0063 and 0075). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use amoxicillin as an active principle in view of the teachings of Bilke or Kurtz, because Bilke teaches amoxicillin is well known in pharmaceutical art as an antibacterial active ingredient (paragraphs 0002-0003), because Kurtz teaches the term antimicrobial includes antibiotics such as amoxicillin (paragraph 0063), and because Autant teaches the use of antibiotic as an active principle in a pharmaceutical dosage form.

Claims 12-14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Autant et al. US 6,022,562, in view of Bilke et al. US 2003/0186956 A or Kurtz et al. US 2003/0138397 A, and Percel et al. US 6,451,345.

Autant is relied upon for the reason stated above. Autant does not explicitly teach the claimed plasticizer and the claimed surfactant.

Parcel teaches microcapsules comprising antibiotic coated with polymer, wetting agent (surfactant) includes sodium lauryl sulfate (column 2, lines 59 through column 3, lines 1-22; and column 4, line 27), and plasticizer includes triethyl citrate and dibutyl sebacate (example 3). Parcel also teaches microcapsules further comprises a seal coat and an enteric coat (column 2, lines 25-27; and column 3, lines 27-64). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the microcapsule of Autant using the surfactant, plasticizer, and an additional enteric coating in view of the teaching of Percel, because Percel teaches microcapsules that can mask the taste of antibiotic and also provide sustained/modified release characteristics, because Autant teaches the use of antibiotic as an active principle in a pharmaceutical dosage form, and because Autant teaches microcapsules having sustained/modified release profiles.

Claims 19 and 24-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Autant et al. US 6,022,562, in view of Bilke et al. US 2003/0186956 A or Kurtz et al. US 2003/0138397 A, and Crowley GB 2 005 538 A.

Autant in view of Bilke or Kurtz are relied upon for the reason stated above. Autant does not expressly teach the combination of amoxicillin and clavulanate.

Crowley teaches formulations comprising 20-1500 mg of amoxicillin together with 20-500 mg of clavulanate, and wherein the weight ratio of amoxicillin and clavulanate is 6:1 to 1:1 (page 1, lines 10-23). The formulation is prepared in dosage forms such as tablet, capsule, sachet or the like (page 1, lines 40-42). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine amoxicillin and clavulanate as active principles in view of the teachings of Crowley, because Crowley teaches combination of amoxicillin and clavulanate results in a composition that has a greater storage life (page 1, lines 10-16), and because Autant teaches the use of antibiotic as an active principle in a pharmaceutical dosage form.

Regarding the release profile, the AUC, and the mean plasma recite in claims 19, 27, 33 and 34. Absent of evident on the contrary, the burden is shifted to applicant to show that the microcapsules taught by Autant would not exhibit the claimed properties. It is noted that products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). In the instant application, Autant teaches the use of the same coating composition comprising the same ingredients, and in the same concentrations.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Okada et al., Giannini et al., Shirai et al., Samejima et al., Pollinger et al., and Ebbers et al. are cited as being of interest for the teachings of encapsulated antibiotic agents.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R 6:00 am to 4:30 pm; Thurs. (telework).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Susan T. Tran
Primary Examiner
Art Unit 1615